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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 03/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/577,304

Applicant(s)

MA ET AL.

Examiner

Charles L. Patterson, Jr.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15, 18, 19, 24-44 and 48-57 is/are pending in the application.
- 4a) Of the above claim(s) 24-44, 48 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18, 19 and 50-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Applicant's election without traverse of Group I, claims 1-15, 18, 19 and 50-57 in Paper No. 10 is acknowledged. Claims 24-44, 48 and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10. The examiner inadvertently left claims 24-49 out of the previous restriction requirement. However, because applicant states in their reply to the restriction requirement that "Applicants elect whatever group contains Claim 1" then claims 1-15, 18, 19 and 50-57 are taken as the elected group as claims 24-44, 48 and 49 are drawn to a patentably distinct group.

The examiner has changed the recitations on page 11, lines 9 and 13 from "Figure 8 is" and "Figure 9 is" to "Figures 8A-8H are" and "Figures 9A-9C are", respectively. He has also changed the recitations on page 13, lines 6 and 10 from "Figure 22 show" and "Figure 24 show" to "Figures 22A-22B shows" and "Figures 24A-224B show", respectively. The changes were made because of the labels on the instant figures.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 18, 19 and 50-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The specification discusses in Example 1 activity assays with various enzymes and target molecules. Then on page 57, lines 21-22 it is stated that "results from such screens...are shown in Tables 2-7, and Figures 12, 14, 15, 19, and 25". However nowhere is an explanation given as to what the various notations such as "IdT", "%Tth", "%Tag4M", "HP", "X" mean in the instant tables or the significance of "cycling rate" or "turnover rate" in the instant figures. Without an explanation of this the examiner or one of ordinary skill reading the instant specification cannot evaluate the specification. In providing an explanation applicants should bear in mind that they cannot introduce new matter that is not either in the specification as filed or is known from prior published works.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is indefinite and confusing in the recitation of "hybridizing to said at nucleic acid cleavage substrate". The instant recitation does not make any sense and apparently something was left out.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 and 55-57 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Brow, et al. (A) or Dahlberg, et al. (B). The instant reference teach thermostable polymerase enzyme that has been mutated so as to eliminate all or most of the polymerase activity and retain the 5'-nuclease activity. This falls within the definition of "heterologous functional domain" on page 19 of the specification. The use made of the enzyme, i.e. "provides altered functionality in a nucleic acid cleavage assay", has no bearing on the patentability of the enzyme *per se*, absent a convincing showing to the contrary. The enzyme has "improved nuclease activity", as in claim 9, since the polymerase activity has been removed and therefore nucleic acids molecules will not be filled in to replace those removed by the nuclease. *Thermus thermophilus* enzyme is mentioned in column 18, lines 24-26 and column 42, lines 10-16, respectively.

Claims 1-15, 18, 19 and 50-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Brow, et al. (A) or Dahlberg, et al. (B). The instant references are characterized *supra*. It is not clear whether the regions of the polymerase are from the palm or thumb region but if not it would have been obvious to do so, absent unexpected results. The kits of claims 50-54 are simply the elements necessary to use the enzyme and would have been obvious. The motivation for preparing the enzyme would have been for use in an invader assay or to provide a means for detection of specific nucleic acid sequences as discussed in column 6, lines 17-19, respectively.


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Copies of the instant references have not been sent since they were mentioned in the specification and/or some of the inventors of the references and the instant application are the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
March 15, 2002